

| <b>Defendant</b> | <b>Multisource Drug</b> | <b>Red Book AWP</b> | <b>DOJ<br/>Determined<br/>Actual AWP</b> | <b>Percentage<br/>Spread</b> |
|------------------|-------------------------|---------------------|--|------------------------------|
| B. Braun         | Sodium Chloride         | \$11.33             | \$1.49                                   | 660%                         |
| BMS Group        | Etoposide (Vepesid)     | \$136.49            | \$34.30                                  | 298%                         |
| Dey              | Albuterol Sulfate       | \$30.25             | \$9.17                                   | 230%                         |
| Immunex          | Leucovorin Calcium      | \$137.94            | \$14.58                                  | 846%                         |
| Pharmacia        | Etoposide               | \$157.65            | \$9.47                                   | 1,565%                       |
| Sicor Group      | Tobramycin Sulfate      | \$342.19            | \$6.98                                   | 4,802%                       |
| Watson           | Vancomycin HCL          | \$70.00             | \$3.84                                   | 1,567%                       |

160. The importance of AWP's to generic drugs was recently revealed in a lawsuit filed by Dey against two of the Publishers. Dey is a generic manufacturer, and generic manufacturers largely compete on price because they market products that contain the same active ingredients and are predominantly therapeutically interchangeable. (¶ 9 of Dey Complaint.) A large segment of the generic marketplace for respiratory drugs is comprised of a relatively small number of entities controlling purchase decisions. (¶ 12 of Dey Complaint.)

161. Dey recognizes that the vast majority of prescription drug transactions – as much as 85% – are covered, in whole or in part, by third-party payor reimbursement arrangements such as managed care plans and Medicaid. (¶ 13 of Dey Complaint.) Both Medicaid and the private insurance systems rely on reimbursement formulas that utilize the AWP. (¶¶ 14-16 of Dey Complaint.)

162. Dey has an agreement with First DataBank and Medi-Span to provide the reporting services with AWP pricing information. Pursuant to this agreement (and in order to make Dey's products eligible for reimbursement through Medicaid Programs), Dey has reported WACs and AWP's. (¶¶ 26-32 of Dey Complaint.)

In each case, until the events that have resulted in the present crisis, First DataBank has (except for some inadvertent errors) selected for listing in its published reports the AWP as suggested by Dey. For over ten years, until April 2003, no prices other than those submitted by Dey have been listed by First DataBank as AWP for Dey products in its databases [even though Dey also reported declining WACs for the products].”

(¶ 32 of Dey Complaint; *see also* ¶ 36 of Dey Complaint for similar allegation against Medi-Span.) This has also been the course of dealings between the Publishers and Dey's competitors:

Virtually every drug manufacturer who participates in these reimbursement programs, and against whom Dey competes also communicates their suggested AWP prices to the reporting services. To the best of Dey's knowledge, with few, if any exceptions, First DataBank and Medi-Span have selected and reported the AWP pricing exactly as suggested by these competing manufacturers.

(¶ 37 of Dey Complaint.) *See also* ¶ 47 of Dey Complaint (recounting testimony of First DataBank representative who admits that First DataBank had always accepted the AWPs suggested by the manufacturers).

163. As Dey alleges, providers who dispense generic drugs "are cognizant of, and are highly attentive to, AWPs as reported by the recognized industry compendia published by First DataBank and Medi-Span because of the direct relationship between the level of reimbursement anticipated for the drugs selected and the reported AWPs of those drugs." (¶ 38 of Dey Complaint.) Indeed, Dey admits that it has relied on the Publishers' practice of treating all manufacturers equally by simply reporting whatever AWP a manufacturer submitted. Consequently, Dey alleges that First DataBank and Medi-Span have frustrated Dey's "reasonable expectations" by, for the first time, *independently reporting* an AWP different than that submitted by Dey. (¶ 39 of Dey Complaint.) These allegations become even more emphatic in a section of the Dey Complaint titled "The Immediate Consequences of the Arbitrary Changes:"

Since reimbursement to Dey's customers is, in Medicaid program in many states and in and [sic] insurance programs, most frequently based on the AWP as reported by the reporting services, this arbitrary and capricious reduction by First DataBank and Medi-Span in AWP would result in a drastic reduction in the reimbursement to drug providers who choose to dispense Dey's product. Since there has not been a comparable reduction in the AWP for Dey's competitors, there would be no comparable reduction in the reimbursement the purchasers of competitive products receive.

Because reimbursement for Dey products would be significantly reduced, but reimbursement for those competing products would remain as they have been, Dey is prevented, by First DataBank's

and Medi-Span's arbitrary and capricious acts, from effectively competing in the marketplace.

In fact, within one day of learning that First DataBank and Medi-Span had arbitrarily changed Dey's AWP, Dey has already been contacted by at least nine of its customers complaining about the drastic changes and indicating that, because of those changes, the customers would not be able to purchase Dey products since they could not earn a reasonable profit from the sale of such products.

Further, at least one customer has already indicated that he had canceled all of his purchases presently on order from Dey and was, instead, buying those products from Dey's direct competitors.

..... These providers will cease to purchase and dispense Dey's drugs if the reimbursement for those drugs is a fraction of those obtained from competing companies. Because purchasing decisions are highly concentrated in this industry among wholesalers and group purchasing organizations, this scenario is playing out across the country and threatens to eliminate sales of Dey's products that are covered by Medicaid and insurance reimbursement programs.

(¶¶ 50-54 of Dey Complaint.)

**C. How The AWP Inflation Scheme Impacts Many Private Reimbursement Systems Through PBMs**

164. As previously noted, health plans typically contract with PBMs so that a health plan's participants can obtain brand name drugs from pharmacies or, via mail order, directly from the PBMs. In these contracts, the brand name drugs are priced at the AWP less a certain percentage "discount."

165. PBMs are fiscal intermediaries that specialize in the administration and management of prescription benefit programs. PBM clients include HMOs, employers, preferred provider organizations and other health insurers. Collectively, four PBMs comprise the significant market share of the PBM market. They are: AdvancePCS; Caremark; Express Scripts; and Medco Health. These four companies handle the drug benefits of 210 million people in the United States, or 70 percent of the nation's population.

166. For brand name drugs, PBMs use the inflated AWP set by drug manufacturers as the basis for reimbursements made (i) by health plans to the PBMs for their members' drug

purchases, and (ii) from the PBMs to the pharmacies for the purchases made by health plans' members.

167. The PBMs typically contract with retail pharmacies to reimburse an amount equal to each drug's AWP, less a specified discount, plus a dispensing fee. Because the PBMs consider the contracting relationship with retail pharmacies to be confidential, health plans are never informed of the reimbursement amount to pharmacies. However, the PBM frequently pockets a "spread" or differential between charges paid to pharmacies and collected from clients.

168. For example, clients may be charged the AWP minus 13 percent, but the retail pharmacy may only receive the AWP minus 15 percent, generating an undisclosed 2 percent spread for the PBM. Furthermore, as the example presented demonstrates, PBMs are motivated to, and do, place on their formulary those drugs with inflated AWPs: the greater the AWP inflation, the greater the profit to the PBM based on the 2 percent spread.

169. A similar situation occurs for generic drug pricing based on MAC lists, as the PBM uses one MAC list to charge clients and another MAC list to reimburse pharmacies.

170. Further, PBMs also have mail order services in which case they act as the pharmacy. In this situation, the PBM keeps the spread between the AWP and the list price as there is no intermediary, like a pharmacy, dispensing the drug. The PBMs keep this spread knowing that the AWPs are inflated and not the true AWP.

171. Defendants knew and understood that the PBMs used the *Red Book* and other publications to determine the AWPs of the drugs. Because the drug manufacturers controlled the AWPs published in the *Red Book* and other compendia, the drug manufacturers knew and understood that they could help manipulate the PBMs' profits. The purpose of artificially inflating the PBMs' profits was to create an illegal kickback to the PBMs, funded by health plan and subscriber overpayments.

172. The PBMs deliberately utilize the inflated AWP to overcharge health plans for brand name drugs purchased by their participants and beneficiaries at retail pharmacies. An example of this practice was recently reported in the WALL STREET JOURNAL on March 30, 2003.

According to the JOURNAL article, the AWP for fluoxetine is \$2.66 a pill. With a 60 percent discount off the AWP, that brings the price to \$1.06 a pill the PBM collects from the plan. Express Scripts pays the pharmacy 25 cents a pill and keeps the rest as profit. Express Scripts claims that currently its client pays 60 cents a pill, but since Express Scripts pays a pharmacy 25 cents per pill, it receives almost a 100 percent profit. And at the same time it was making this profit, Express Scripts was notifying its clients it was saving them money by having switched to fluoxetine, instead of Prozac.

**D. Congressional And Other Federal Investigations and Actions**

173. The United States Department of Justice (“DOJ”), the United States General Accounting Office (“GAO”), the Office of the Inspector General at the United States Department of HHS (“OIG”), and certain Congressional subcommittees have been investigating defendants and other pharmaceutical manufacturers for questionable practices regarding the industry’s calculation of AWP’s and for offering illegal incentives to providers.

174. In a letter dated September 28, 2000, sent from the House of Representatives Committee on Ways and Means, Subcommittee on Health, to the President of the trade organization known as the Pharmaceutical Research and Manufacturers of America (most defendants are members of this association), Congressman Stark identified the improper scheme of manipulating AWP’s and noted:

This corruptive scheme is perverting financial integrity of the Medicare program and harming beneficiaries who are required to pay 20% of Medicare’s current limited drug benefit.

175. In his September 28 letter, Congressman Stark made the following five “shocking conclusions”:

First – Certain drug manufacturers have abused their position of privilege in the United States by reporting falsely inflated drug prices in order to create a de facto improper kickback for their customers.

Second – Certain drug manufacturers have routinely acted with impunity in arranging improper financial inducements for their physicians and other healthcare provider customers.

Third – Certain drug manufacturers engage in the fraudulent price manipulation for the express purpose of causing federally funded health care programs to expend scarce tax dollars in order to arrange de facto kickbacks for the drug manufacturers' customers at a cost of billions of dollars.

Fourth – Certain drug manufacturers arrange kickbacks to improperly influence physicians' medical decisions and judgments notwithstanding the severely destructive effect upon the physician/patient relationship and the exercise of independent medical judgment.

Fifth – Certain drug manufacturers engage in illegal price manipulation in order to increase utilization of their drugs beyond that which is necessary and appropriate based on the exercise of independent medical judgment not affected by improper financial incentives.

176. The DOJ and Congressional investigations are ongoing.

#### **E. Examples Of Specific AWP Inflation By Each Defendant**

177. Due to each defendant's acts of concealment, the following examples of specific unlawful conduct are merely illustrative and are not intended to constitute an exhaustive account of all of the unlawful activity engaged in by each defendant. Additional detail is peculiarly within each defendant's control thereby warranting further discovery into each drug identified in this Amended Complaint as well as other drugs for which any defendant has published an AWP.

178. Defendants are each charged with inflating the AWP for the drugs identified below *and* for those identified in Appendix A.

##### **1. Amgen**

179. Amgen engages in an organization-wide and deliberate scheme to inflate AWP's. Amgen has stated fraudulent AWP's for all or almost all of its drugs, including those set forth below.

| Brand Name<br>(if applicable) | Generic Name            | Therapeutic Category/Usage  |
|-------------------------------|-------------------------|---|
| Aranesp                       | darbepoetin alfa albumi | Antianemic Agent; Blood Modifier<br>Used in the treatment of anemia associated with chronic renal failure and/or chemotherapy |

| Brand Name<br>(if applicable) | Generic Name  | Therapeutic Category/Usage   |
|-------------------------------|---------------|--|
| Enbrel                        | etanercept    | Antirheumatic Agent<br>Used to reduce signs and symptoms of<br>rheumatoid arthritis  |
| Epogen <sup>1</sup>           | epoetin alfa  | Antianemic Agent; Blood Modifier<br>Used in the treatment of anemia associated<br>with chronic renal failure, chemotherapy<br>and/or HIV-infected patients |
| Kineret                       | Anakinra      | Antirheumatic Agent<br>Used in the treatment of moderate to severe<br>rheumatoid arthritis   |
| Neulasta                      | Pegfilgrastim | Antineoplastic; Blood Modifier<br>Used to decrease incidence of infection<br>(neutropenia) in some cancer patients   |
| Neupogen                      | Filgrastim    | Antineoplastic; Blood Modifier<br>Used to decrease incidence of infection<br>(neutropenia) in some cancer and leukemia<br>patients                         |

180. The specific drugs manufactured and/or distributed by Amgen for which relief is currently sought in this case are set forth below or in Appendix A.

181. Amgen controlled and set the AWP's for all of its drugs, including those appearing in Appendix A, through direct communications with industry compendia.

182. Amgen's scheme to inflate its reported AWP's and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by the State of Nevada and Nevada citizens.

**a. Amgen's understanding of AWP and intentional manipulation thereof**

183. Internally, Amgen defines AWP as "the common basis for reimbursement by payors" and "one of the factors used by Medicare to determine payment for drug charges." (Press Release, "Data from Study Shows Aranesp ...", Dec. 9, 2002 ([www.amgen.com](http://www.amgen.com)).)

184. Amgen was well aware that its customers' profits depended on reimbursement rates for drugs, and that Amgen's own sales and profits in turn depended on its customers' reimbursement payments and profits:

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<sup>1</sup> In the Medicare Part B context, reimbursement for Epogen is not based on the AWP, but rather on a specific dollar amount set by statute. However, non-Medicare Part B reimbursement for Epogen is based on AWP.



Our sales depend on payment and reimbursement from third-party payors, and a reduction in the payment rate or reimbursement rate could result in decreased sales of our products.

In both domestic and foreign markets, sales of our products are dependent, in part, on the availability of reimbursement from third-party payors ...we believe that sales of Aranesp and Neulasta are and will be affected by government and private payor reimbursement policies. ... If reimbursement for our marketed products changes adversely or if we fail to obtain adequate reimbursement for our other current or future products, health care providers may limit how much or under what circumstances they will administer them, which could reduce the use of our products or cause us to reduce the price of our products. This could result in lower product sales or revenues ....

(Amgen 2002 Form 10-K at 43-44).

185. Amgen also knows that several of its drugs compete with other manufacturers' drugs. In some cases, as detailed herein, the competing manufacturers' manipulate the AWP to create a reimbursement advantage for their drugs. Specifically, Amgen's Kineret competes with J&J's Remicade and Immunex's Enbrel; Neupogen competed against Immunex's Leukine; and Aranesp competes against Procrit, J&J's epoetin alfa product. *See* Amgen's 2001 Form 10-K (P002327-002397). All of these competing drugs are alleged herein to be subject to AWP manipulation. The logical inference is that Amgen also engaged in AWP manipulation for those drugs where the competitors were manipulating and marketing the AWP spread.

186. Amgen also made sure its sales representatives were focused on reimbursement and customer profit motives. A senior Amgen sales manager has publicly stated:

Reps need to understand the insurance system flawlessly. They need to understand the money trail in terms of how a drug gets reimbursed, who reimburses it, and coverage or policy limitations – those are fundamental questions.”

187. Amgen has also established a website ([www.reimbursementconnection.com](http://www.reimbursementconnection.com)) to help providers with reimbursement issues, including information on how to calculate reimbursement for Amgen drugs and Sample Reimbursement Sheets detailing how much Medicare will pay for Amgen drugs. In addition, Amgen maintains a telephone Reimbursement Hotline for providers or their office staffs to call to get help with reimbursement questions.



**b. Amgen provided other improper incentives**

188. In addition to marketing the spread, Amgen has utilized other impermissible inducements to stimulate sales of its drugs. These inducements were designed to result in a lower net cost to the provider while concealing the actual wholesale price beneath a high invoice price.

189. A 1993 OIG Report detailed how Amgen gave substantial year-end rebates to its customers based on their purchases of Epogen. The report noted that Medicare and Medicare beneficiaries did not receive the benefit of any rebates; all monies remained with the provider. There was no way to provide for any rebates on Medicare claim forms, and Amgen's rebates were not provided until year-end:

[T]he effect of the rebates is that it reduces the actual cost of EPO to a dialysis facility, thus increasing their gross profit. Presently, the rebates represent price reductions which benefit the facilities exclusively.

("Review of Epogen Reimbursement," (OIG A-01-02-00506 at 7-8)).

190. By utilizing hidden inducements, Amgen provided purchasers with substantial discounts meant to gain their patronage while maintaining the fiction of a higher wholesale price.

191. Amgen's scheme to inflate its reported AWP's and market the resulting spread to increase the market share of its drugs and its use of hidden rebates and financial inducements to its customers has resulted in excessive overpayments by the Nevada Medicaid Program and Nevada citizens.

**c. Amgen concealed its AWP manipulation**

192. Amgen deliberately acted to conceal its fraudulent reporting and marketing of the AWP spread. For example, as noted above, Amgen gave rebates to its Epogen customers which effectively lowered the true price charged. When OIG asked Amgen for data on its total sales or the total amount of Epogen rebates, Amgen refused to provide such data. ("Review of Epogen Reimbursement," (OIG A-01-02-00506 at 7-8)).

193. In September 2001, the GAO reported that epoetin alfa accounted for the second highest percentage of Medicare expenditures on drugs in 1999, accounting for 9.5% of spending for prescription drugs by Medicare in 1999 and for 3.4% of all Medicare allowed services.

## 2. AstraZeneca

194. AstraZeneca engages in an organization-wide and deliberate scheme to inflate AWP's. AstraZeneca has stated fraudulent AWP's for all or almost all of its drugs, including those set forth below.

| Brand Name<br>(if applicable) | Generic Name                              | Therapeutic Category/Usage  |
|-------------------------------|---|---|
| Accolate                      | zafirlukast                               | Leukotriene Antagonist (Respiratory Agent)<br>Used in the treatment of asthma   |
| Armindex                      | anastrozole                               | Antiestrogen (Antineoplastic: Hormonal Agonist/Antagonist)<br>Used in the treatment of breast cancer in postmenopausal women                                    |
| Atacand                       | candesartan cilexetil                     | Angiotension II Receptor Antagonist (Cardiovascular Agent)<br>Used in the treatment of hypertension   |
| Atacand HCT                   | candesartan cilexetil-hydrochlorothiazide | Angiotension II Receptor Antagonist With Diuretic (Cardiovascular Agent)<br>Used in the treatment of hypertension   |
| Casodex                       | bicalutamide                              | Antineoplastic<br>Used in the treatment of prostate cancer  |
| Diprivan                      | propofol                                  | General Anesthetic<br>Used in the induction or maintenance of anesthesia as part of balanced anesthetic technique   |
| Entocort                      | budesonide                                | Glucocorticoid<br>Used in the treatment of Crohn's disease  |
| Nexium                        | esomeprazole magnesium                    | Proton Pump Inhibitor (Gastrointestinal Agent)<br>Used in the treatment of heartburn and erosive esophagitis  |
| Nolvadex                      | tamoxifen citrate                         | Antiestrogen (Antineoplastic: Hormonal Agonist/Antagonist)<br>Used in the treatment or prevention of breast cancer  |
| Prilosec                      | omeprazole                                | Proton Pump Inhibitor (Gastrointestinal Agent)<br>Used in the treatment of gastric and duodenal ulcers, gastroesophageal reflux disease and erosive esophagitis |

| Brand Name<br>(if applicable) | Generic Name         | Therapeutic Category/Usage  |
|-------------------------------|----------------------|---|
| Pulmicort                     | budesonide (inh)     | Glucocorticoid<br>Used for maintenance treatment of asthma  |
| Rhinocort                     | budesonide (nasal)   | Glucocorticoid<br>Used in the treatment of allergic rhinitis  |
| Seroquel                      | quetiapine fumarate  | Antipsychotic Agent (Psychotherapeutic Agent)<br>Used in the treatment of schizophrenia   |
| Toprol                        | metoprolol succinate | Beta Adrenergic Blocking Agent (Cardiovascular Agent)<br>Used in the treatment of hypertension, angina pectoris and heart failure                     |
| Zestril                       | lisinopril           | Angiotension Converting Enzyme Inhibitor (Cardiovascular Agent)<br>Used in the treatment of hypertension and heart failure                            |
| Zoladex                       | goserelin acetate    | Gonadotropin Releasing Hormone Analogue (Antineoplastic: Hormonal Agonist/Antagonist)<br>Used in the treatment of prostate and advanced breast cancer |
| Zomig                         | zolmitriptan         | Serotonin Receptor Agonist (Migraine Preparation)<br>Used in the treatment of migraines   |

195. The specific drugs manufactured and/or distributed by AstraZeneca for which relief is currently sought in this case are set forth below or in Appendix A.

196. AstraZeneca controlled and set the AWP's for all of its drugs, including those appearing in Appendix A, through direct communications with industry compendia. In one internal marketing memorandum, AstraZeneca recommended:

We take a price increase in December 1995. By doing this, we can inform the Red Book of this increase and it will go into the Red Book for January 1996. This is critical, so that the state Medicare carriers can recognize our new price in January. Typically, the state carriers use the January Red Book and the July Red Book for their reimbursement price of Medicare reimbursed products. Last year when we took the price increase in February there were some Medicare carriers who did not change their reimbursement price until September. Also TAP notifies Red Book 1 month before the price change. We are at a competitive disadvantage with our audience.

(AZ0021838) (Highly Confidential).

197. AstraZeneca's scheme to inflate its reported AWP's and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by the State of Nevada and Nevada citizens.

**a. AstraZeneca's understanding of AWP and intentional manipulation thereof**

198. In AstraZeneca's Guide to Coverage and Reimbursement, AstraZeneca defines AWP as follows:

Average Wholesale Price (AWP): The composite wholesale price charged on a specific commodity that is assigned by the drug manufacturer and is listed in either the Red Book or Blue Book. AWP is often used by third-party payers as a basis for reimbursement.

(AZ0052597) (Confidential). Thus, by its own definition, AstraZeneca recognizes that: (i) AWP should be an average of actual wholesale prices; (ii) the drug manufacturers control the published AWP; and (iii) the published AWP's directly affect the payments made by third-party payers including the Nevada Medicaid Program.

199. Several documents illustrate AstraZeneca's pattern of inflating AWP's. For example, in one internal marketing memorandum, AstraZeneca recognized the profits to providers from the inflation of AWP's: "The market we are in wants a more expensive Zoladex, because the doctor can make more money." (AZ0021838) (Highly Confidential).

200. Similarly, in its agreements with PBMs, AstraZeneca guaranteed that it would maintain a spread between AWP and AWC (average wholesale cost) in order to ensure a profit to PBMs. (AZ0036207) (Highly Confidential). In its agreement with Caremark, AstraZeneca stated:

ZENECA WILL REIMBURSE CAREMARK FOR THE DIFFERENCE BETWEEN THE AMOUNT COLLECTED BY CAREMARK ON EACH PATIENT UNIT SOLD AND AWP AT THE TIME THE UNIT WAS DISPENSED. CAREMARK WILL HAVE EXERCISED BEST EFFORTS TO COLLECT THE FULL AWP FROM THE 3RD PARTY PAYER AND THE PATIENT PRIOR TO SUBMISSION TO ZENECA.

(AZ0036208) (Highly Confidential).

201. AstraZeneca recognized that it caused Third-Party Payors and Patients to overpay:

BECAUSE OF OUR STEEP DISCOUNTING, NEARLY HALF THE PROFIT TO BE REALIZED WITH ZOLADEX IS PAID BY MEDICARE. AND SINCE MEDICARE IS THE QUICKEST AND MOST DEPENDABLE PAYOR, THIS WAS SEEN AS AN ENORMOUS BENEFIT. THE OTHER HALF OF THE PROFIT WAS FROM THE PATIENT CO PAY OR SECONDARY INSURANCE . . . .

(AZ0037011) (Highly Confidential).

202. Documents regarding AstraZeneca's Zoladex provide particularly brazen examples of AWP manipulation. The documents reveal intense competition with TAP Pharmaceuticals and its drug Lupron, focusing primarily on the spreads available to physicians between Zoladex and Lupron.

203. For instance, one internal chart touts the greater spread that can be reaped from the inflated AWP for Zoladex over the AWP for Lupron:

|                       | <b>AWP</b> | <b>AWP minus 5%</b> | <b>Current Cost (1 depot)</b> | <b>Return to Practice 1 depot</b> | <b>Current Max Discount 29.5% vs 50%</b> | <b>Return to Practice at Max.</b> |
|-----------------------|------------|---------------------|-------------------------------|-----------------------------------|--|-----------------------------------|
| Lupron 3-month depot  | \$1,622.68 | \$1,541.55          | \$1,297.50                    | \$244.05                          | \$915.00                                 | \$626.55                          |
| Zoladex 3-month depot | \$1,231.53 | \$1,169.95          | \$985.22                      | \$184.73                          | \$492.61                                 | \$677.34                          |

(AZ 0055816) (Highly Confidential).

204. Another document announcing new pricing for Zoladex states:

With a purchase of 72+ depots of ZOLADEX and the additional 2% for paying within 30 days yields the doctor a \$133.67 profit margin with ZOLADEX vs \$133.50 with a purchase of 101+ depots of Lupron. For those offices that purchase between 60-100 depots of Lupron monthly, they can increase their profit margin greatly by purchasing ZOLADEX.

(AZ 0037019) (Highly Confidential).

205. Moreover, AstraZeneca repeatedly tried to educate providers regarding the Medicare reimbursement system and the benefits to the providers for Zoladex utilization. For example in a document sent to providers AstraZeneca states:

The following is a cost comparison of Zoladex® vs Lupron® 7.5 mg where Zoladex® is purchased under the buying power of the Urology Purchasing Group, St. Louis, Mo. The calculations reflect prices/discounts effective as of 2/1/94.

|  | ZOLADEX                         | LUPRON                          |                                 |                                 |                                 |
|--|---------------------------------|---------------------------------|---------------------------------|---------------------------------|---------------------------------|
| Quantity   | 1                               | 1-11                            | 12-25                           | 26-50                           | Year<br>Office                  |
| Direct Drug Cost   | \$245.97                        | \$371.00                        | \$360.99                        | \$352.50                        | \$                              |
| Medicare & Claim   | \$344.76<br>x 80%               | \$463.75<br>x 80%               | \$463.75<br>x 80%               | \$463.75<br>x 80%               | \$463.75<br>x 80%               |
| Medicare Payment to MD   | \$275.81                        | \$371.00                        | \$371.00                        | \$371.00                        | \$371.00                        |
| Patient / 3rd Party<br>Payment*  | \$344.76<br>-275.81<br>\$ 68.95 | \$463.75<br>-371.00<br>\$ 92.75 | \$463.75<br>-371.00<br>\$ 92.75 | \$463.75<br>-371.00<br>\$ 92.75 | \$463.75<br>-371.00<br>\$ 92.75 |
| Medicare Claim Direct Drug<br>Cost   | \$344.76<br>-245.97             | \$463.75<br>-371.00             | \$463.75<br>-360.99             | \$463.75<br>-352.50             | \$463.75<br>-                   |
| Total Profit Per Injection   | \$ 98.79                        | \$ 92.75                        | \$103.75                        | \$111.25                        |                                 |
| Difference   |                                 | \$ 6.04                         | \$ 4.96                         | \$ 12.46                        | \$                              |
| Percent Profit per Injection   | 40%                             | 25%                             | 29%                             | 32%                             | %                               |
| Additional Cost outlay of<br>Lupron vs Zoladex (Direct<br>Cost vs Direct Cost) |                                 | \$125.03                        | \$114.03                        | \$106.53                        | \$                              |

ILLUSTRATION: If your office uses between 12 and 25 Lupron® units per month, your total "profit" per injection, over Zoladex, is \$4.96 but your additional outlay per Lupron injection is \$114.03. This represents an unnecessary tie up of corporation monies. Based on 12 Lupron injections per month, your office has "tied up" \$1,368.36 to achieve a "profit" of \$59.52. In this example, Zoladex represents a 40% return on investment vs. 29% for Lupron.

\* Calculations assume a 100% collection of monies from patient or 3rd party. If Lupron® is used instead of Zoladex® and the 20% is not collected, then the office has lost \$23.30 per injection (\$92.75 - \$68.95 = \$23.80).

01-25-0418

(AZ0046085) (Highly Confidential).

206. Other internal documents reveal that AstraZeneca was directly marketing the spread to physicians. A memo announcing price changes for Zoladex states:

We have raised AWP and AWC by 7% and have increased our discount level higher at all purchasing tiers.

Pricing on Zoladex 3-month is as follows:

| Discount      |    | AWP     | Cost   |
|---------------|----|---------|--------|
| 1-5 depots    | 0  | 1206.49 | 966.79 |
| 6-11 depots   | 11 | 1206.49 | 860.44 |
| 12-23 depots  | 15 | 1206.49 | 821.77 |
| 24-47 depots  | 17 | 1206.49 | 802.44 |
| 48-59 depots  | 20 | 1206.49 | 773.43 |
| 60-71 depots  | 22 | 1206.49 | 754.10 |
| 72-96 depots  | 24 | 1206.49 | 734.76 |
| 96-191 depots | 25 | 1206.49 | 725.09 |
| 192 +         | 30 | 1206.49 | 676.75 |

Zoladex AWP has been priced at a 5% premium above 3 times the Zoladex 1-month depot. The discount levels have been increased also.

(AZ 0024566-67) (Highly Confidential)

207. Thus, at the same time AstraZeneca was raising the AWP for Zoladex, it was lowering the real price to providers (by giving bigger discounts), which served to widen the spread.

208. Another document sets forth the difference between the purchase price and the AWP at various volume levels. Note that even with no volume discount, a provider is still making at least a \$71.00 profit per unit on Zoladex ( $\$358.55 - 286.84 = 71.71$ ):

NEW LOWER CASE QUANTITY DISCOUNT  
ZOLADEX PRICING

| UNITS | AWP      | COST     | DISCOUNT | LESS 2%  |
|-------|----------|----------|----------|----------|
| 1-5   | \$358.55 | \$286.84 | 0%       | \$281.10 |
| 6-11  | \$358.55 | \$269.63 | 6%       | \$264.24 |
| 12-23 | \$358.55 | \$261.02 | 9%       | \$255.80 |
| 24-47 | \$358.55 | \$252.42 | 12%      | \$247.37 |
| 48-59 | \$358.55 | \$243.81 | 15%      | \$238.93 |
| 60-71 | \$358.55 | \$235.21 | 18%      | \$230.50 |
| 72+   | \$358.55 | \$229.47 | 20%      | \$224.88 |

(P003060.)

209. The same document goes on to tout the practice's ability to make more profit, or return on investment, by exploiting the AWP scheme:



Thank you for your time and listening ear on Monday, April 17. As discussed, I am offering a proposal to switch Lupron patients to Zoladex. Zeneca Pharmaceuticals now has new volume pricing, with a 20% maximum discount, for Zoladex. What this will offer the practice is an opportunity to save money, realize a better return on investment, achieve the same profit you currently have with our competitor and free up a substantial amount of working capital. Zoladex will also save the patient money and the system money.

Based on a comparison of Zoladex and Lupron, if 480 depots are used annually Zoladex will save the practice \$57,177.60 a year. Your dollar return to the practice is now slightly higher with Zoladex. This rate of return for Zoladex is now 59% compared to Lupron's 39%

(P003058.)

210. Another AstraZeneca document even more explicitly demonstrates to providers how they can profit from the AWP scheme, in excess of \$64,000 per year:

| ZOLADEX   |                         |                       |     |
|---|-------------------------|-----------------------|-----|
| Direct Pricing  | Medicare AWP            | \$\$Return / % Return |     |
| 72+ \$224.88  | \$358.55                | \$133.67              | 59% |
| 72x\$224.88=\$16,191.38   | 72x\$358.55=\$25,815.60 | \$9,624.24            | 59% |
| <i>based on your use of 480 depots annually, with our 2% discount these are the comparisons</i> |                         |                       |     |
| \$107,942.40  | \$172,104.00            | \$64,161.60           | 59% |

(P003058.)

211. According to a September 2001 GAO report, the discount from AWP for medical providers who purchased AstraZeneca's Zoladex and billed Medicare was between 21.9% and 22.3%. ("Payments for Covered Outpatient Drugs Exceed Providers' Cost, Sept. 2001"

(P005546-78).)

**b. AstraZeneca provided other improper incentives**

212. AstraZeneca, through its employees and agents, also provided millions of dollars worth of free samples of its drugs to providers. The free samples would be used to offset the total cost associated with purchases of its drugs, thereby increasing the spread, while also

concealing the actual cost of the drug. Moreover, at least as to Zoladex®, AstraZeneca sales representatives specifically told providers that they could and should bill for the free samples.

213. A written proposal from AstraZeneca Sales representative Randy Payne dated July 17, 1995 encourages a urology practice to switch all of their patients to Zoladex and states: “AS AN ADDED INCENTIVE, ZENECA WILL PROVIDE YOU WITH 50 FREE DEPOTS (over \$11,900 worth of product) FOR THE INITIAL CONVERSION TO ZOLADEX.” (P003059.)

**c. AstraZeneca has been the target of multiple government investigations**

214. In connection with its scheme to inflate AWP, AstraZeneca has been investigated by the United States Department of Justice. In January 2002, a federal grand jury in Wilmington, Delaware returned an indictment accusing a New Jersey doctor of conspiring with AstraZeneca to resell free samples of Zoladex® that AstraZeneca sales representatives had given the doctor. The indictment alleges that AstraZeneca (i) sold Zoladex® to the New Jersey doctor and others at prices substantially below the AWP reported by AstraZeneca, and (ii) provided the New Jersey doctor with materials showing how much more profit he could make by using Zoladex® instead of its competitor, Lupron®.

215. In response to the government’s subpoena, AstraZeneca appears to have produced documents related to Zoladex only.

216. An investigation into AstraZeneca’s marketing practices for Zoladex from 1991 through 2002 by the United States Attorney’s Office for the District of Delaware revealed that AstraZeneca (i) provided free Zoladex samples to certain providers, knowing and expecting that those providers would prescribe and administer the free drug samples to their patients and bill those free samples to Medicaid; (ii) provided illegal remuneration to certain providers in the form of free Zoladex, unrestricted educational grants, business assistance grants and services, travel and entertainment, consulting and audit services, and honoraria; and (iii) marketed a “Return-to-Practice” program in which AstraZeneca inflated the AWP, deeply discounted the

price paid by providers and then marketed the spread between the AWP and the discounted price as additional profit to be returned to the provider's practice from Medicare and Medicaid's reimbursements for Zoladex.

217. In June 2003, AstraZeneca pled guilty to a criminal conspiracy to violate the Prescription Drug Marketing Act (21 U.S.C. §§ 333(b) and 331(t)) and agreed to a \$63,872,156 criminal fine. In addition, AstraZeneca agreed to pay over \$190 million in civil damages and penalties to the Medicare and Medicaid programs.

218. As further evidence of the artificial nature of its AWP's, in late 2001 or early 2002, AstraZeneca raised the AWP across the board for most drugs on Appendix A. It did so without any corresponding change in product or service, and without any increase in the DP paid by purchasers.

### **3. The Aventis Group (Aventis, Pharma, Hoechst and Behring)**

219. Aventis engages in an organization-wide and deliberate scheme to inflate AWP's. Aventis has stated fraudulent AWP's for all or almost all of its drugs, including those set forth below.

| Brand Name<br>(if applicable) | Generic Name                    | Therapeutic Category/Usage   |
|-------------------------------|---------------------------------|--|
| Allegra                       | fexofenadine                    | Antihistamine<br>Used for the relief of symptoms of seasonal allergic rhinitis                       |
| Allegra-D                     | fexofenadine<br>pseudoephedrine | Antihistamine<br>Used for the relief of symptoms of seasonal allergic rhinitis                       |
| Amaryl                        | glimepiride                     | Antidiabetic<br>Used to lower blood glucose in Type II diabetes patients                             |
| Anzemet                       | dolasetron mesylate             | Antineoplastic<br>Used to prevent nausea and vomiting after chemotherapy or operation                |
| Arava                         | leflunomide                     | Antirheumatic<br>Used in the treatment of active rheumatoid arthritis                                |
| Azmacort                      | triamcinolone<br>aceonide (inh) | Steroidal Anti-Inflammatory Agent<br>(Respiratory Agent)<br>Used for maintenance treatment of asthma |

| Brand Name<br>(if applicable) | Generic Name                    | Therapeutic Category/Usage  |
|-------------------------------|---------------------------------|---|
| Calcimar                      | calcitonin salmon               | Parathyroid Agent<br>Used in the treatment of blood calcium levels and to increase the level of calcium in the bones        |
| Carafate                      | sucralfate                      | Duodenal Ulcer Adherent Complex (Gastrointestinal Agent)<br>Used in the treatment and maintenance therapy of duodenal ulcer |
| Cardizem                      | diltiazem                       | Calcium Channel Blocker (Cardiovascular Agent)<br>Used in the treatment of angina and hypertension                          |
| Gammar PL.V.                  | immune globulin                 | Immunizing Agent<br>Used as a maintenance therapy in patients with compromised immune systems                               |
| Intal                         | cromolyn sodium                 | Antiasthmatic<br>Used to treat allergic rhinitis and severe perennial bronchial asthma                                      |
| Nasacort                      | triamcinolone acetonide (nasal) | Steroid Anti-Inflammatory Agent (Nasal Preparation)<br>Used for nasal treatment of allergic rhinitis symptoms               |
| Taxotere                      | Docetaxel                       | Antineoplastic<br>Used in the treatment of breast or lung cancer after failed chemotherapy                                  |
| Trental                       | Pentoxifylline                  | Blood Viscosity-Reducing Agent (Blood Modifier)<br>Used to improve the flow of blood through blood vessels                  |

220. The specific drugs manufactured and/or distributed by Aventis for which relief is currently sought in this case are set forth below or in Appendix A.

221. Aventis controlled and set the AWP's for all of its drugs, including those appearing in Appendix A, through direct communications with industry compendia. For example, on December 29, 1997, Rhone-Poulenc Rorer (a subsidiary of Rhone Poulenc SA, which merged with Hoechst AG to form Aventis in 1999) submitted a list of AWP price increases effective January 1, 1998 to both Medi-Span and First DataBank. Aventis instructed Medi-Span and First DataBank to "change [their] records accordingly to reflect the new prices." (AV-AAA-001054) (Confidential). Similar letters requesting price changes for 1999 were sent

to Medi-Span and First DataBank by Aventis on December 29, 1998. (AV-AAA-001047) (Highly Confidential), (AV-AAA-001050) (Highly Confidential), and price changes for 1997 on December 23, 1996 (AV-AAA-001066) (Highly Confidential). Further, an April 1, 1998 letter from Centeon notifies Medical Economics (the *Red Book*) that effective April 1, 1998, it “has raised AWP pricing” for Bioclade and Monoclade. (ABAWP 005314) (Highly Confidential).

222. Aventis’s scheme to inflate its reported AWP and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by the State of Nevada and Nevada citizens.

**a. Aventis’s understanding of AWP and intentional manipulation thereof**

223. Internal documents recently produced by Aventis reveal the definition of AWP used and understood by Aventis and its predecessor companies. Specifically, a November 1992 internal newsletter at Armour Pharmaceutical Company (a predecessor company to Centeon LLC, later known as Aventis Behring) states:

“AWP” is common language among insurance carriers (state, federal and private). The acronym stands for Average Wholesale Price. AWP’s are set by manufacturers as a “suggested retail” for the products they produce. *These figures represent a reasonable profit margin to healthcare providers and as such are widely referenced by insurance carriers when setting reasonable and customary rates of reimbursement.*

Average Wholesale Prices are printed in Red Book Drug Topics and Blue Book. Both serve as data resources to all state Medicaid programs. Each publication lists the drugs by brand name in alphabetical order with its corresponding descriptions.

(ABAWP 008990-91) (Highly Confidential) (emphasis added).

224. Aventis possessed the *Red Book*’s definition of Average Wholesale Price:

Average wholesale price (AWP) is the standardized cost of a drug, which managed care plans frequently use for determining drug benefits. The AWP is determined through reference to a common source of price information, such as the American Druggist’s *Blue Book*, which lists the costs charged for an undiscounted drug to a pharmacy by a large group of pharmaceutical wholesale suppliers. AWP’s are set by pharmaceutical manufacturers and supplied to all pricing DataBanks for publication.

(ABAWP 012067) (Highly Confidential).

225. Aventis knew that AWP manipulation, and the related marketing of an AWP spread, was improper. An internal Aventis (Centeon) document, in pertinent part, states – in large, bold print:

**ATTENTION!**

**SELLING AGAINST AWP**

This is not an option.

Traditionally, some manufacturers have promoted differences in AWP as a means to sell their products. Centeon does not do this, and we hope to hear from you if you learn that any other manufacturer (sic) are using this tactic.

Some pharmaceutical manufacturers set high AWP as a means of securing market shares for their drugs. Although not illegal, the intensity of government scrutiny of this and other pharmaceutical manufacturer pricing practices is increasing. The inspector general is looking at prices for big-ticket drugs

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At the risk of being redundant it is imperative to stress that AWP can not (sic) be used in the content of selling any of our products. If you are made aware, either orally or through written correspondence, of any manufacturer using this form of sales tactic immediately report such findings to Gene Hull and appropriate steps will be taken.

(ABAWP 000855) (Highly Confidential).

226. Nonetheless, Aventis (Centeon) routinely promoted differences in AWP in marketing its numerous products. In seminar materials used in conjunction with an “Oncology University Anzemet Workshop” held in 1998, Aventis explained to attendees how its AWP spread could be exploited. Aventis offered the following definition and example of AWP spread:

**SPREAD**

- Difference between acquisition cost (AC) and reimbursement (Profit, Margin, etc.).

- Example for Anzemet

- AC = \$68 for 100 mg vial
- AWP = \$166.50
- AWP – 5% = \$158.18
- 80/20 = \$126.54/\$31.64
- Spread = \$58.54 + \$31.64 = \$90.18

(AV-AAA-02242-56) (Highly Confidential).

227. Aventis distributed a “Reimbursement Spreadsheet” to be utilized by its sales personnel to demonstrate to “private practice office” customers the “financial advantages” of its drug, Anzemet, compared to Zofran and Kytril based on Aventis’ established AWP and acquisition price (total reimbursement through Medicare). (AV-AAA-001190-93) (Highly Confidential). Aventis also communicated to its sales staff on December 7, 1998 that “Anzemet still [held] the advantage on spread” following a Kytril price increase. (AV-AAA-002291) (Highly Confidential).

228. Another Aventis internal document also addresses how a particular Aventis customer might increase its margin choosing Anzemet over the competition:

Cost and Reimbursement: OnCare has negotiated a very favorable contract with Hoechst Marion Roussel [an Aventis predecessor company], manufacturer of Anzemet. Our cost from OTN for the Anzemet 100 mg/ml vial is reduced from approximately \$70 ea. to \$62.50. In addition there will be quarterly rebates further reducing the cost to \$61.25. The AWP is \$149.88, making the margin \$88.63. Additional returns can be realized by using 1.8 mg/kg as recommended in the package insert. For example, for a patient weighing 70Kg, the dose is 126 mg, requiring 2 vials. Since the vial is single use, you may bill for both vials: total cost is \$122.50, the AWP is \$299.76, the net is \$177.26 (assuming reimbursement at AWP). By comparison the current margin for 0.7 of Kytril is \$54.89. For 1 mg it is \$78.42. If there is a price increase in 1999 (which we expect) our prices are protected, however the AWP will go up, further increasing the margin. The contract makes Anzemet the preferred 5-HT3 antiemetic drug for OnCare.

(AV-AAA-001523) (Highly Confidential). Other customers received promotional materials reflecting a significant spread between the unit price and AWP for Anzemet – and touting a “Reimbursement and Patient Assistance Program Hotline.” (AV-AAA-001619-23) (Confidential).



229. Similarly, Aventis increased AWP's for its Gammar product line to keep provider and intermediary reimbursement levels competitive with those created by the inflated AWP's of other manufacturers. A May 8, 1996 Aventis (Centeon) Interoffice Correspondence memo states:

Effective June 1, 1996, we will be revising our AVERAGE WHOLESALE PRICE for our Gammar P iv product line. We are implementing this change based on feedback from the field. Alpha and Bayer have recently increased their AWP pricing on Gammimmune 10% and Venoglobulin S 10%. They are presently priced at \$75 and \$80 per gram respectively. . . . This change will help us maintain a competitive balance in the marketplace.

(ABAWP 004767) (Highly Confidential).

230. Centeon interoffice correspondence, dated June 23, 1999, reveals that a Centeon employee provided a representative of First DataBank with the following information regarding Centeon's AWP for Gammar:

She asked me to validate Centeon's AWP and wholesale list price for Gammar PIV 5 and 10 gram vials.

\*\*\*

I gave her the following info:

"Currently it is not Centeon's business practice to sell Gammar PIV to wholesalers. But should a wholesaler place an order, our wholesale list price is \$52/gram, or \$260 for 5 gram vial, and \$520 for 10 gram vial."

"Centeon's suggested AWP is \$400 for 5 gram vial, and \$800 for 10 gram vial. This is pricing as reported to First DataBank, but we do not sell product at these prices."

(ABAWP 005315) (Highly Confidential).

231. In response to government subpoenas, Aventis produced numerous price lists setting forth spreads between AWP's and prices offered to wholesalers, providers and other intermediaries. A review of those price lists reveals that Aventis has consistently offered drugs and other solutions to its customers at prices significantly below the published AWP and that the

spread was of great importance to its customers. To repeat every one of those drugs and the spread offered to each specific customer here is not practical.

232. A March 4, 1997 price list issued by Arcola Laboratories (a division of Rhonel-Poulenc Rorer Pharmaceuticals sets the AWP for Calcimar (calcitonin-salmon) at \$31.35, with a cost of \$12.00 – for a spread of 161%. (AV-AAA-000705) (Highly Confidential).

233. Additional evidence of the phony nature of this defendant's AWP's arises from its manipulation of its reported AWP's in late 2000 and 2001, when it increased its reported AWP's for certain of the drugs identified in Appendix A across the board without any change in product or service offered. If these AWP's were real, price increases would not be uniform and would bear a relationship to some product change. At the same time of these price increases, cost to providers did not increase, further evidencing the phony nature of the AWP's. The specific drugs subject to this manipulation were Allegra, Allegra-D, Amaryl, Anzemet Tablets, Arava Tablets, Azmacort, Carafate Tablets and Suspension, DiaBeta, Intal, Lantus, Lasix, Nasacort, Nasacort AQ, Tilade, and Trental.

**b. Aventis provided other improper incentives**

234. Aventis, through its employees and agents, also provided free samples of its drugs to providers. (ABAWP 000089) (Highly Confidential) (ABAWP 000811) (Highly Confidential). The free samples would be used to offset the total cost associated with purchases of its drugs, thereby increasing the spread, while also concealing the actual cost of the drug. In fact, a 1995 "SALES AND FREE GOODS STATUS" memo reveals that Aventis (Armour) issued millions of "free goods units" to a single customer alone. (ABAWP 000220-25) (Highly Confidential).

**c. Aventis has been the target of multiple government investigations**

235. In connection with its scheme to inflate AWP's, Aventis has been investigated by the United States Department of Justice, the Office of Inspector General of the Department of Health and Human Services, the Commerce Committee of the U.S. House of Representatives, the Attorney General for the State of Texas, the Attorney General for the State of California, and the State of California Department of Justice Bureau of Medi-Cal Fraud and Elder Abuse.

236. In a report published by the DHHS (AB-00-86), the DOJ documented at least 15 instances where the published AWP for various dosages of 4 drugs manufactured by Aventis were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the 4 drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by Aventis in the 2001 *Red Book*.

| Drug                                     | 2001 <i>Red Book</i> AWP | DOJ Determined Actual AWP | Difference | Percentage Spread |
|--|--------------------------|---------------------------|------------|-------------------|
| Anzemet Injectable (dolasetron mesylate) | \$166.50                 | \$74.08                   | \$92.42    | 125%              |
| Factor VIII/ Bioclone                    | \$1.25                   | \$.91                     | \$.34      | 37%               |
| Factor VIII/ Helixate                    | \$1.18                   | \$.78                     | \$.40      | 51%               |
| Gammar (immune globulin)                 | \$400.00                 | \$296.67                  | \$103.33   | 35%               |

(P006299-P006316).

237. An OIG report (*see* "Medicare Reimbursement of Prescription Drugs," OEI-03-00-00310, Jan. 2001) further revealed that: (i) the AWP for all immune globulin 5 mg doses listed in the 1997 *Red Book* were inflated by an average spread of 32.21%; (ii) a 10 mg dose of Anzemet had a Medicare Median of \$14.82 and a Catalog Median of \$8.29, resulting in a spread of 78.76%; and (iii) a 20 mg dose of Taxotere had a Medicare Median of \$283.65 and a Catalog Median of \$8.29, resulting in a spread of 18.75%. (P006398-006424).

238. A government investigation revealed inflated pricing implemented by Aventis with respect to the injectable form of Anzemet. In a September 28, 2000 letter to Alan F. Holmer, President of the Pharmaceutical Research and Manufacturers of America, U.S. Rep. Pete Stark provided a synopsis of the scheme implemented by Aventis (Hoechst):

The following chart represents a comparison of Hoechst's fraudulent price representations for its injectable form of the drug versus the truthful prices paid by the industry insider. It is [sic] also compares Hoechst's price representations for the tablet form of Anzemet and the insider's true prices. It is extremely interesting that Hoechst did not create a spread for its tablet form of Anzemet but only the injectable form. This is because Medicare reimburses Doctors for the injectable form of this drug and by giving them a

profit, can influence prescribing. The tablet form is dispensed by pharmacists, who accept the Doctor's order. And this underscores the frustration that federal and state regulators have experienced in their attempts to estimate the truthful prices being paid by providers in the marketplace for prescription drugs and underscores the fact that, if we cannot rely upon the drug companies to make honest and truthful representations of their prices, Congress will be left with no alternative other than to legislate price controls.

| NDC No:      | Unit Size/<br>Type        | Quantity | Net Price as<br>Represented<br>to Florida<br>Medicaid | True<br>Wholesale<br>Price | Variance  |
|--------------|---------------------------|----------|---|----------------------------|---|
| 0088-1206-32 | 100 mg/5 ml<br>Injectable | 1        | \$124.90  | \$70.00                    | Represented price 78%<br>higher than true<br>wholesale price. |

(P007548-007588).

239. U.S. Rep. Thomas J. Bliley, in a May 4, 2000 letter to the CEO of Aventis (Behring), also stated concerns regarding Aventis' pricing of Gammar:

The Office of Inspector General (OIG) at the Department of Health and Human Services determined that the Medicare-allowed amount for immune globulin, a pharmaceutical product sold by your company under the name Gammar, in Fiscal Year 1996 was \$42.21. The OIG further estimated that the actual wholesale price of this drug was \$16.12 and the highest available wholesale price that the OIG was able to identify was \$32.11.

(P006962-P006966).

**d. Aventis concealed its AWP manipulation**

240. Aventis deliberately acted to conceal its fraudulent reporting and marketing of the AWP spread. For example, in response to a May 26, 1995 fax request from *Red Book*, Aventis refused to provide Wholesale Acquisition Cost (WAC) for products it listed in the *Red Book* database – in spite of *Red Book's* assurances that WAC information would be distributed via electronic means only. (ABAWP 008420) (Highly Confidential). Aventis effectively hid the AWP spread.

#### 4. The Boehringer Group

241. The Boehringer Group engages in an organization-wide and deliberate scheme to inflate AWP's. The Boehringer Group has stated fraudulent AWP's for all or almost all of its drugs, including those set forth below.

| Brand Name<br>(if applicable) | Generic Name              | Therapeutic Category/Usage   |
|-------------------------------|---------------------------|--|
| Viramune                      | nevirapine                | Antiviral Agent (Anti-Infective Agent)<br>Used in the treatment of HIV infection   |
|                               | acycolvir sodium          | Anti-Infective Agent<br>Used in the treatment of herpes infections   |
|                               | amikacin sulfate          | Antibiotic Agent (Anti-Infective Agent)<br>Used to treat respiratory tract, urinary tract, bone, skin and soft tissue infections |
|                               | cytarabine                | Antineoplastic<br>Used to treat leukemia and non-Hodgkin's lymphoma  |
|                               | doxorubicin hydrochloride | Antineoplastic<br>Used in the treatment of ovarian cancer and AIDS-related Kaposi's sarcoma                                      |
|                               | etoposide                 | Mitotic Inhibitor (Antineoplastic)<br>Used in the treatment of testicular neoplasm and small cell cancer of the lung             |
|                               | leucovorin calcium        | Antianemic Agent (Blood Modifier)<br>Used in the treatment of anemia   |
|                               | methotrexate sodium       | Antineoplastic<br>Used in the treatment of various forms of cancer   |
|                               | mitomycin                 | Antineoplastic<br>Used in the treatment of various forms of cancer   |
|                               | vinblastine               | Antineoplastic<br>Used in the treatment of various forms of cancer, including lymphoma and breast cancer                         |
|                               | vinblastine sulfate       | Antineoplastic<br>Used in the treatment of various forms of cancer, including lymphoma and breast cancer                         |

242. The specific drugs manufactured and/or distributed by The Boehringer Group for which relief is currently sought in this case are identified below or set forth in Appendix A.

243. The Boehringer Group controlled and set the AWP's for all of its drugs, including those below and appearing in Appendix A, through direct communications with industry compendia. For example, a September 27, 1996 document entitled "*Red Book* Product Listing Verification" required Defendant to sign each page that contained a list of The Boehringer Group's products, NDC numbers, AWP's, WAC's and price effective dates. (MDL BV 000799). Similarly, a *Red Book* New Product Information Form dated November 25, 1996 was completed by Bedford for the drug Ketamine Hydrochloride Injection USP and required Bedford to fill in the AWP and WAC for the product (which it did). (MDL BV 000807).

244. Despite its actual verification of the AWP's in the *Red Book*, The Boehringer Group claims that it does not set "AWP's" but nonetheless agrees that the "terms 'average' and 'wholesale' are the standard dictionary definitions." In a letter dated August 20, 1999 to the Chairman of the Committee on Commerce regarding "Response to Request for Pricing Information, July 19, 1999" ("Bedford's AWP Response"), counsel for Bedford Laboratories stated as follows:

***Please provide all definitions of AWP used by your company since January 1, 1996 for the purpose of determining the reimbursement price for Medicare-covered drugs, and all records relating to those definitions. In particular, please provide the specific definitions you apply to the terms "average" and "wholesale."***

Answer: The term "AWP", which we interpret as meaning Average Wholesale Price, is not used by Bedford Laboratories in pricing any of its products. Moreover, Bedford has not and does not take into account the "reimbursement price for Medicare-covered drugs" in pricing any of its products. Rather than use AWP, Bedford established a Hospital Price List for its products. The Hospital Price List refers to the price a customer without a contract, who is not a wholesaler or distributor, would pay for Bedford's products. It also refers to a suggested price that a wholesaler charges its customers. This terminology is used because the majority of Bedford's customers, particularly for drugs such as Leucovorin, are hospitals.

The pharmaceutical reporting services, such as Redbook, independently identify Bedford's Hospital Price List as AWP. The prices Bedford charges its wholesale customers are referred to at Bedford as Wholesale Price Lists, which are identical for all of Bedford's wholesale customers. These prices are identified by the

pharmaceutical reporting services as Wholesale Acquisition Cost (“WAC”). *Given its pricing terminology and practices, Bedford’s definitions of the terms “average” and “wholesale” are the standard dictionary definitions.*”

(MDL BV 001941-1944, at 1941-1942) (Confidential) (emphasis added).

245. Notwithstanding its attempt to distance itself from its published AWP, The Boehringer Group effectively ratified the AWP set by its predecessors. In Bedford’s AWP Response, counsel responded:

... Bedford performs no AWP calculation for Leucovorin, 50 mg and did not do so during calendar year 1998. . . . This price was established by Chiron Therapeutics, which prior to May, 1996, had the marketing responsibilities for this product. Bedford took over those responsibilities in May of 1996 and continued the price established by Chiron. Prior to that time, Ben Venue, Bedford’s parent, only manufactured this product. For that reason, Bedford is not aware of how Chiron originally priced this product.

(MDL BV 001941-1944, at 1942) (Confidential).

246. Of course, depending on which government entity was performing the investigation and the date of the government’s inquiries, The Boehringer Group’s “definition” of AWP changed. By November 2, 1999, Bedford told the Committee on Commerce that it understood AWP to be tied to “the manufacturer’s suggested prices to customers of its customers.” (MDL BV 006761-65, at 6763).

247. In a letter dated June 5, 2000 to the Nevada Attorney General regarding the Attorney General’s inquiries about Bedford’s AWP, Bedford responded in pertinent part:

**1. Identify what Bedford represents to be its understanding of the meaning “AWP.”**

Answer: Bedford’s understanding of AWP, derived from its experience in the industry, is that it is a suggested price identified by pharmaceutical companies as the price a wholesaler may wish to charge its customers for pharmaceutical products. Bedford has always viewed AWP as a suggested ‘retail’ price to the customers of wholesalers and not as an acquisition cost to wholesalers.

**2. Does Bedford report AWP to First Databank for all its products? With what frequency? How is that information communicated?**



Answer: Bedford does not use the term AWP in its business, ***except as a semantical concession*** to those who, like the price reporting services, have reported Bedford's Hospital List Price ("HLP") as an AWP. Upon request by FDB, Bedford provides its price lists, which consist of the HLPs and Wholesale List Prices ("WLPs") for its products. \*\*\*\*

Bedford reports this information, usually by facsimile, at least once a year, and more frequently upon request by FDB.

(MDL BV 002071-73, at 2072) (Confidential) (emphasis added).

248. In fact, even armed with the knowledge that industry compendia use Bedford's HLPs as AWP, Bedford admits that HLPs do not accurately reflect the AWP for its drugs:

As indicated above, Bedford does not communicate AWP for its products. However, it is aware that pharmaceutical price reporting services have chosen to report Bedford's HLP as AWP. Bedford has always reported its HLP accurately. ***These list prices are not averages of the wholesale prices for Bedford's products.***

(MDL BV 002071-73, at 2073) (emphasis added).

249. In practice, Bedford did in fact acknowledge that its HLPs should be used as AWP in the industry compendia. For example, a June 17, 1996 fax cover sheet from Bedford to Medispan states: "[S]ee corrections noted for select products on the AWP cost!" (MDL BV 000770) (Confidential). Attached to this cover sheet is Bedford's Hospital Price List dated May 1, 1996 in which certain prices are crossed out and replaced with typewritten prices. (MDL BV 000771-780) (Confidential). Similar cover sheets with the same notation and the same price lists were also sent to First DataBank (MDL BV 000774-780, MDL BV 000781-785) (Confidential) ("[S]ee corrections made on select products for the AWP!") and *Red Book* (MDL BV 000793-95) (Confidential) ("Corrections made on the AWP for select products!").

250. The Boehringer Group's scheme to inflate its reported AWP and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by the State of Nevada and Nevada citizens.